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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/817,781	03/26/2001	Paul C. Harris	2065.2001-000	7810
21005	7590	04/02/2004	EXAMINER	
HAMILTON, BROOK, SMITH & REYNOLDS, P.C. 530 VIRGINIA ROAD P.O. BOX 9133 CONCORD, MA 01742-9133			NGUYEN, BAO THUY L	
			ART UNIT	PAPER NUMBER
			1641	

DATE MAILED: 04/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/817,781

Applicant(s)

HARRIS ET AL.

Examiner

Bao-Thuy L. Nguyen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 January 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-11,13-15,33-41 and 43-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-11,13-15,33-41 and 43-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicant's amendment filed 1/20/04 has been received. Claims 12 and 42 have been cancelled. Claims 1, 4-11, 13-15, 33-41 and 43-45 are pending.

Rejection Withdrawn

2. The rejection of claims 1, 4-15 and 33-45 under 35 U.S.C. 102(b) as being anticipated by Kuo (EP0 895 084 A2) is withdrawn in view of the amendment to claims 1 and 33 to specifically recites that the control capture reagent reacts with analyte-binding particles but does not interact with the analyte of interest or with the analyte-binding agent on the analyte-binding particles.

New Rejection

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4. Claims 1, 4-11 and 13-15 are rejected under 35 U.S.C. 102(a) as being anticipated by Polito et al (WO 00/31538).

Polito discloses the invention substantially as claimed. Polito teaches a test strip comprising a separation pad, a conjugate pad, a test zone, a control zone and an absorbent pad. The test strip is made of cellulose, nitrocellulose or nylon, etc. (page 8, lines 14-27). The

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conjugate pad contains a population of first analyte binding agent and analyte non-specific binding agent, both coupled to a detection agent such as latex or gold sol particles. (page 9, lines 7-15 and page 10, line 1 through page 11, line 24). Polito teaches the analyte non-specific binding agent is selected for its ability to bind to substances other than the analyte of interest (page 11, lines 25-27), and may be an antigen, an organic molecule, a hapten conjugated to a protein non-specific for the analyte of interest, BSA or dinitrophenol (page 12, lines 3-15). Polito specifically teaches that the analyte non-specific agent comprises a control-binding agent, selected so as to bind specifically to molecules other than the molecules that bind to the analyte of interest. In this way, these control-binding agents can bind to the control zones (page 12, lines 16-26 and page 13, lines 4-13). Polito teaches that the analyte binding zones contains immobilized binding agent for the analyte of interest (page 14, lines 1-13). In use, sample is applied to the separation pad and allows to migrate through the various zones of the test strip. Any complexes between analyte and labeled binding agent is captured in the detection zone and the remaining conjugate is captured at the control zone through binding of the control binding agent to the analyte non-specific binding agent on the particles (page 17, line 3 through page 18, line 18). Polito teaches measuring the intensity of the test zone relative to that of a the control zone and the result expressed as a ratio (page 19, lines 1-17).

Claim Rejections - 35 USC § 103

5. Claims 33-41 and 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Polito (WO 00/31538) in view of Kuo et al (US 6,436, 721).

See the discussion of Polito. This reference differs from the instant claims because it fails to specifically teach the step of correcting the analyte-binding particle amount by taking a ratio

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of the amount of label detected in the detection zone to the sum of the amount of labels in the detection zone and the control zone.

Kuo, however, teaches an assay substantially as claimed. Kuo also teaches that signals from the detectable label in the second region (sample capture zone) and from the detectable label in the third region (control capture zone) are measured and the ratios of these signals is determined and related to the amount of the analyte in the sample. Kuo teaches that such a determination provides the advantage of an increase in accuracies, because it corrects for inaccuracies in labeled conjugate deposition and/or non-uniform flow through the matrix (column 4, lines 21-40). Kuo also teaches a method in which the summation of the signal from both the sample capture and control capture zone is taken, and the ratio of the signal in the sample capture zone and the sum is used to determine the amount of analyte (column 5, lines 4-13).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the analysis taught by Kuo in the method of Polito because Polito teaches that while the result of the assay may be measured as a density of reflectance or absolute amount, the reported result is more meaningful in other units such as ratios. A skilled artisan would have had a reasonable expectation of success in using the analysis method taught by Kuo in the assay of Polito because Kuo teaches that by using the ratios of signals in both test zone and control zone one can corrects for inaccuracies in labeled conjugate deposition and/or non-uniform flow through the matrix.

Response to Arguments

6. Applicant's arguments with respect to claims 1 and 33 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

US 6,133,048 teaches a reagent comprising a direct particulate label co-sensitized with a specific binding agent for an analyte and a non-specific protein which participate in a control reaction with another specific binding agent which does not bind to the first specific binding agent. '048 also teach test strip and method of using the same.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

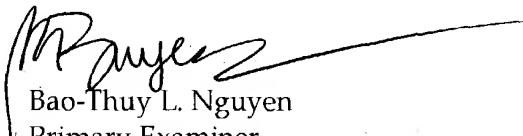
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Tuesday and Thursday from 9:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Bao-Thuy L. Nguyen
Primary Examiner
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